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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/633,111 | 08/04/2000 | Jan Carlsson | 1614-0238P | 2114 |

24256 7590 08/26/2003

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| EXAMINER |
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NGUYEN, BAO THUY L

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| ART UNIT | PAPER NUMBER |
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1641

DATE MAILED: 08/26/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/633,111

Applicant(s)

CARLSSON ET AL.

Examiner

Bao-Thuy L. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 02, 2003 has been entered.

Claim Rejections - 35 USC § 112

2. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because it is unclear how the ion-exchange functional groups participate in the assay method. Do they facilitate the separation of the different components in a sample? If so, how?

Claim Rejections - 35 USC § 103

3. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pristoupil for reasons of record in the previous office action, paper no. 13.

Pristoupil discloses the general trends in the development of chromatographic and electrophoretic techniques, and specifically teaches the use of nitrocellulose membrane filters. Pristoupil teaches the use of nitrocellulose membrane having pore size ranging from about 0.01 μm to 10 μm in chromatography and electrophoresis separation of proteins and nucleic acids

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(pages 109-110). Pristoupil disclose a chamber for membrane chromatography where chromatography in aqueous solutions is performed in a horizontal position (page 112, figure 1). The samples are applied on the test strip and after separation, proteins and nucleic acids are visualized by either the sandwich techniques or dyes. Pristoupil discloses that nitrocellulose membranes impregnated with a suitable antigen can be used for the rapid detection, saturation or quantitative determination of specific antibodies in micro amounts of materials (page 119).

Pristoupil differs from the instant invention in failing to specifically state that the polymeric membrane is attached to a liquid-impervious backing. However, Pristoupil teaches the membrane is lay flat on a glass plates in a chromatography chamber; therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the polymeric membrane of Pristoupil by attaching it directly to the glass plates because it is well known in the art that such backing provides the advantage of increased handling strength for the membrane. Pristoupil is considered to make obvious the instant claims because steps f2a through f2c of claim 1 are seen to be optional.

Pristoupil also differs from the instant invention in failing to specifically recites a membrane comprising the ion-exchange functional groups of claim 1; however, Pristoupil does specifically teach a membrane having ion-exchange functional and since it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value

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of a result effective variable in a known process is ordinarily within the skill of the art."

Application of Boesch, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980). Since Applicant has not disclosed that the specific limitations recited in instant claims (the specific ion-exchange functional groups) are for any particular purpose or solve any stated problem and the prior art teaches that nitrocellulose membranes may be impregnated with various ion-exchange functional groups and often vary according to the sample being analyzed and the assay conditions, and that these functional groups can be chosen and altered according to specific needs, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures known in the chromatography art.

Response to Arguments

4. Applicant's arguments filed 28 April 2003 have been fully considered but they are not persuasive.

Applicant argues that any contribution from ion-exchange to the binding of the proteins in Pristoupil is minimal and cannot be compared to the ion-exchange groups recited in amended claim 1, by which the instant invention achieves full ion-exchange chromatography using nitrocellulose.

This argument has been fully considered but is not persuasive. As stated above, the function or action of the ion-exchange groups recited in claim 1 has not been properly recited. Even though applicant appears to argue that the ion-exchange groups bind the proteins and aid in their separation, this is not recited in the claims. The claim recites that only a part of the

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matrix contains the ion-exchange functional groups and thus, it is unclear if this is the same "part" that is used in the chromatography assay.

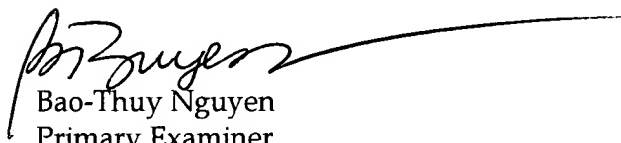
Conclusion

5. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (703) 308-4243. The examiner can normally be reached on Monday, Wednesday and Thursday from 9:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 and (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Bao-Thuy Nguyen
Primary Examiner
23 July 2003